LEGAL GUIDANCE

REIMPORTATION OF PHARMACEUTICALS

The Food and Drug Administration (FDA), settling an issue stemming from federal legislation passed four years ago, has given the Armed Services a green light to return surplus pharmaceutical items from bases located in foreign countries to the United States for further military use.

Congress, in 1987, enacted the Prescription Drug Marketing Act (Public Law 100-293). In pertinent part, this law amended section 801 of the Food, Drug and Cosmetic Act to prohibit the reimportation of U.S.-produced pharmaceuticals except by the original manufacturer of the product or as authorized by the Secretary of Health and Human Services for emergency purposes. This reimportation ban was intended to prevent foreign counterfeit drugs, falsely described as reimported U.S.-produced items, from entering the pharmaceutical distribution system. In addition, Congress found that proper storage and handling of legitimate prescription drugs cannot be guaranteed by U.S. law once the pharmaceuticals have left the boundaries of the United States. The FDA has the responsibility of enforcing this ban.

Since its inception, the scope of the reimportation ban has not been entirely clear. The title of the law and the purposes behind it suggested that it should apply only to cases involving the marketing or commercial trading of prescription drugs. However, the language actually used by Congress is reasonably open to a broader interpretation and, if adopted, would prohibit most transfers or shipments of U.S.-made items from a foreign country to the United States.

At the conclusion of hostilities in the Persian Gulf, deployed Naval medical units retained on hand large quantities of unused pharmaceuticals for which the United States was the country of origin. Due to the uncertainty as to the scope of the reimportation ban imposed by the Prescription Drug Marketing Act, it was originally feared that this law might require the Navy to leave these medical products in the theatre of operations. This would have been a costly result since these drugs would not then be available to supplement the pharmaceutical inventories of the Navy's stateside hospitals and clinics and replacement purchases would be necessary. Fortunately, in response to a request by the Naval Medical Logistics Command for an advisory opinion, the FDA has determined that the Prescription Drug Marketing Act does not present a bar to the return of surplus prescription drugs from overseas military bases where they were stocked in support of OPERATION DESERT STORM.

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